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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,476	04/01/2004	Teresa Elisa Virgina Silva Cabezon	VU60111	1568

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EXAMINER	
YAEN, CHRISTOPHER H	
ART UNIT	PAPER NUMBER
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/816,476	CABEZON ET AL.	
	Examiner	Art Unit	
	Christopher H. Yaen	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RE: CABEZON ET AL.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, and 8-10, drawn to an immunogenic fragment of Cripto and to an immunogenic composition comprising an immunogenic fragment of Cripto, classified in class 530, subclass 300. Note if applicant elects this group for prosecution on the merits, applicant is additionally required to elect a single polypeptide sequence from Seq Id No: 3 or 4. This election should NOT be construed as an election of species because each of the recited and claimed sequences are functionally and structurally distinct.

II. Claims 4-7, drawn to an isolated polynucleotide sequence, an expression vector, a recombinant viral or bacterial delivery system, and a host cell comprising the isolated polynucleotide, classified in class 536, subclass 23.1, for example. Note if applicant elects this group for prosecution on the merits, applicant is additionally required to elect a single polynucleotide encoding a single polypeptide sequence from Seq Id No: 3 or 4. This election should NOT be construed as an election of species because each of the recited sequences are functionally and structurally distinct.

III. Claim 11, drawn to a method for the treatment of cancer in a patient comprising the administration of an immunogenic composition of group I,

classified in class 424, subclass 184.1. Note if applicant elects this group for prosecution on the merits, applicant is additionally required to elect a single polypeptide sequence from Seq Id No: 3 or 4. This election should NOT be construed as an election of species because each of the recited and claimed sequences are functionally and structurally distinct.

IV. Claims 12,19, and 20, drawn to a method of stimulating T-cells specific for Cripto and a method of inducing an immunoresponse to Cripto comprising the administration of a composition comprising a fragment of Cripto, classified in class 514, subclass 2. Note if applicant elects this group for prosecution on the merits, applicant is additionally required to elect a single polypeptide sequence from Seq Id No: 3 or 4. This election should NOT be construed as an election of species because each of the recited and claimed sequences are functionally and structurally distinct.

V. Claim 13, drawn to a population of T-cell specific for a fragment of Cripto, classified in class 435, subclass 325.

VI. Claims 14-15, drawn to a method of inhibiting the development of cancer in a patient comprising incubating CD4+ and or CD8+ T-cells isolated from a patient with Seq Id No: 97 and administering the T-cells to the patient, classified in class 424, subclass 277.1 .

VII. Claims 16-18, drawn to a method of producing an immunogenic response to Cripto comprising the administration of a component comprising a polynucleotide encoding Seq Id No: 97, classified in class 514, subclass 44.

2. The inventions are distinct, each from the other because of the following reasons:

3. The polypeptide of group I and polynucleotide of group II are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Furthermore, searching the inventions of groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. As such, it would be burdensome to search the inventions of groups I and II together.

The polypeptide of group I, the polynucleotide of group II and the T-cell population of group V are patentably distinct for the following reasons. The inventions of group I , group II and group V are related in the sense that the polypeptide of group I is used to sensitize the cellular population of group V, while the T-cell population of group V is specific for the polypeptide of group I. Aside from this relationship, the peptide does not share any structural and or functional relationship with the T-cell population thus any relationship between a polypeptide of group I and T-cell population of group V is dependent upon the interaction between the peptide and the T-cells. With regard to the polynucleotide, the polynucleotide is not related to the cell except for the fact that the polynucleotide may be encoded with a cell.

Furthermore, searching the inventions of group I, group II, and group V would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and a T-cell population which interacts with the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the T-cell populations of group V. Furthermore, polypeptide sequences of group I may be known even if a T-cell population of group V is novel. In addition, the technical literature search for the polypeptide of group I and the T-cell population of group V are not coextensive, e.g., polypeptides may be characterized in the technical literature prior to discovery or manufacture or isolation of T-cell populations.

Inventions I and VI, and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of inhibiting the development of cancer comprising the administration of CD4 and or CD8 positive cells (group VI) and the method of producing an immunogenic response to Cripto comprising the administration of a component comprising a polynucleotide encoding Seq Id No: 97 (group VII) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for each of the claimed inventions differ significantly for each of the materials. For the method of group VI, T-cells are employed, while the method of group VII require the administration of polynucleotides. Both of these methods do not require the use of the polypeptide of group I. For these reasons the Inventions I, VI and VII are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups I, VI, and VII have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups I, VI, and VII together.

Inventions II and III, IV, and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different

modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of treating cancer comprising the administration of a polypeptide fragment (group III), a method of stimulating T-cell specific for Cripto comprising the contacting of T-cells with a polypeptide (group IV), and a method of inhibiting the development of cancer comprising the administration of T-cells (group VI) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for each of the claimed inventions differ significantly for each of the materials. For the method of group III, a polypeptide fragment of Cripto is required, for the method of group IV, again a polypeptide fragment of Cripto is required, while the method of group VI requires the administration of T-cells. These methods do not require the use of the polynucleotide of group II. For these reasons the Inventions II, III, IV, and VI are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups II, III, IV, and VI have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups II, III, IV, and VI together.

Inventions I and III and IV are related as product and process of of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of group I can be used to make antibodies that are specific for the polypeptide.

Searching the inventions of Groups I and III and IV together would impose serious search burden. The inventions of Groups I and III and IV have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polypeptide and the method of treating cancer comprising the administration of a polypeptide fragment and a method of stimulating T-cell comprising the contacting of a cell with a polypeptide fragment are not coextensive. Group I encompasses molecules which are claimed in terms of amino acid sequence, which are not solely required for the search of Group III and IV. In contrast, the search for group III and IV would require a text search for the method of treating cancer and stimulating a T-cell response in addition to an amino acid search of the polypeptide. Prior art which teaches an identical polypeptide would not necessarily be applicable to the method of using the polypeptide. Moreover, even if the polypeptide were known, the method of using the product may be novel and unobvious in view of the preamble or active steps.

Inventions II and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the

polynucleotide can be used to make recombinant proteins as opposed to being used as a stimulant in an immune response.

Searching the inventions of Groups II and VII together would impose serious search burden. The inventions of Groups II and VI have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polynucleotide and the method of stimulating an immune response using a polynucleotide are not coextensive. Group II encompasses molecules which are claimed interms of nucleotide sequence, which are not solely required for the search of Groups VI and or X. In contrast, the search for group VII would require a text search for the method of stimulating an immune response in addition to a search for the polynucleotide. Prior art which teaches a polynucleotide would not necessarily be applicable tothe method of using the polynucleotide. Moreover, even if the polynucleotide product were known, the method of using the product may be novel and unobvious in view of the preamble or active steps.

Inventions III , IV, VI, and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The methods groups III, IV, VI, and VII are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials

necessary for each of the claimed inventions differ significantly for each of the materials. For these reasons the Inventions IV-VI and VIII-X are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups III, IV, VI, and VII together.

Inventions IV, and V, VI the inventions of group V and VII are unrelated because the product of groups V and the methods of IV,VII are not used or otherwise involved in the process.

Inventions V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cells can be used to purify peptide fragments which are capable of recognizing specific T-cell receptors.

Searching the inventions of Groups V and VI together would impose serious search burden. The inventions of Groups V and VI have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the T-cells and the method of stimulating an immune response using a T-cells are not coextensive. Group V encompasses molecules which are claimed in terms of moleculr profile or receptor expression, which are not solely required for the search of Groups VI.

In contrast, the search for group VI would require a text search for the method of stimulating an immune response in addition to a search for the specific T-cell. Prior art which teaches a T-cell specific for Cripto would not necessarily be applicable to the method of using the T-cell. Moreover, even if the product were known, the method of using the product may be novel and unobvious in view of the preamble or active steps. The inventions are distinct, each from the other because of the following reasons:

4. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re*

Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher Yaen
Art Unit 1643
January 8, 2007

CHRISTOPHER H. YAEN
PRIMARY EXAMINER